Sterile Compounding Supplemental

Type of compounding performed

Simple_____ Moderate_____ Complex_____ Hazardous_____

Pharmacy License #_____

RULE	PHARMACY AREA STANDARDS	C	NC	NA
239	Commercially available products only compounded according to Rule 239.04.b.			
239	FDA list is monitored.			
239.02.a	All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer.			
239.02.b	Certificate of Analysis.			
239.02.c	Appropriate equipment and utensils are available, clean, and in good working order.			
239.03	Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited.			
	Master Formulation Record and the Compounding Record has been reviewed.			
	POLICIES AND PROCEDURES			
239.05.a.i	Appropriate training, packaging, handling, transport, and storage requirements.			
239.05.a.ii	Accuracy and precision of calculations, measurements, and weighing.			
239.05.a.iii	Determining ingredient identity, quality, and purity;			
239.05.a.iv	Labeling accuracy and completeness;			
239.05.a.vi	Auditing for deficiencies.			
239.05.a.viii	Safe limits and ranges.			
240.07.a	Antiseptic hand cleansing.			
240.07.b	Disinfection of non-sterile compounding surfaces.			
240.07.c	Selecting and appropriately donning protective garb.			
240.07.d	Maintaining or achieving sterility of sterile products while maintaining the labeled strength of active ingredients;			
240.07.e	Manipulating sterile products aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence;			
240.07.f	Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile product.			
240.07.g	Inspecting for quality standards before dispensing or distributing.			
	DOSAGE FORMS REQUIRING STERILITY			
240.02	Aqueous bronchial and nasal inhalations, except sprays intended to treat bronchial mucosa only; Baths and soaks for live organs and tissues Injections Irrigations for wounds and body cavities Ophthalmic drops and ointments Tissue implants.			
	Compounder Responsibility			
240.03	Compounders and sterile prepackagers are responsible for ensuring opened or partially used packages of ingredients for subsequent use must be properly stored.			
240.03.a.i	Opened or entered single-dose containers, shall be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded;			
240.03.a.ii	Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture.			
240.03.a.iii	Opened single-dose ampules shall not be stored for any time period;			
240.03.a.iv	Multiple-dose containers that are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives, may be used for up to twenty-eight (28) days .			
240.03.b	Water-containing compounded sterile products that are non-sterile must be sterilized within six (6) hours after completing the preparation.			
240.03.c	Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated areas where components and ingredients of sterile products are prepared.			

RULE	PHARMACY AREA STANDARDS	C	NC	NA
240.04	Maintaining environmental quality control.			
240.04.a	Hoods and aseptic environmental control devices must be certified at least every six (6) months or if relocated.			
240.04.b	Filters inspected and replaced.			
	STERILE PRODUCT PREPARATION EQUIPMENT.			
240.05	*Protective apparel *Sink with hot and cold water in close proximity to the hood *Refrigerator for proper storage of additives and finished sterile products. *Appropriate laminar airflow hood or other aseptic environmental control device.			
	DOCUMENTATION REQUIREMENTS			
240.06.c.iv	Audits appropriate for the risk of contamination for the particular sterile product including: * Visual inspection. * Periodic hand hygiene and garbing competency. *Media-fill test procedures evaluation at least annually.			
240.06.c.iv	Environmental sampling testing at least every six (6) months * Total particle counts. * Viable air sampling. * Gloved fingertip sampling. * Surface sampling. * Sterility testing of high risk batches of more than twenty-five (25) identical packages.			
240.06.d	Temperature, logged daily.			
240.06.e	Beyond use date and accuracy testing.			
240.06.f	Measuring, mixing, sterilizing, and purification equipment inspection.			
	HAZARDOUS COMPOUNDING			
241.01	Storage and compounding areas have sufficient general exhaust ventilation.			
241.02	Utilize a ventilated cabinet designed to reduce worker exposures.			
241.02.a	Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design.			
241.02.b	If asepsis is not required, a Class I BSC, powder containment hood or an isolator intended.			
241.03	Clearly identified storage areas, containers, prepared doses.			
241.05	Protective equipment and supplies, including spill kit.			
	personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs.			
	PARENTERAL ADMIXTURE LABELING			
142	01. Ingredient Information. 02. Date and Time. The date and time of the addition, 03. Identification. The initials or other unique identifier of the pharmacist. 04. Prescribed Administration Regimen. The rate or appropriate route. 05. Special Instructions.			
	LABELING OF DISTRIBUTED COMPOUNDED DRUG PRODUCT			
144	Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription.			
144	01. Drug Name. The name of each drug included. 02. Strength or Concentration. The strength or concentration of each drug. 03. Base or Diluents. If a sterile, the name and concentration of the base or diluents. 04. Administration. the dosage form or route of administration. 05. Quantity. 06 The expiration or beyond use date. 07. Compounder Identifier. The initials or unique identifier. 08. Resale. If: *A pharmacy "not for further dispensing or distribution *An outsourcing facility "not for resale."			

C=COMPLIANT NC=NOT COMPLIANT NA=NOT APPLICABLE

Board Compliance Officer	Pharmacist Signature	Date